

Intragam® 10

Human Normal Immunoglobulin 10% (10 g/100 mL), solution for intravenous infusion.

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Intragam® 10. It does not take the place of talking to your doctor. It does not contain all the available information about Intragam® 10.

All medicines have risks and benefits. Your doctor has weighed the benefits of you receiving Intragam® 10 against the possible risks.

If you have any concerns about receiving this medicine, ask your doctor. Follow your doctor's advice even if it is different from what this leaflet says.

Please read this leaflet carefully and keep it as you may need to read it again.

The information in this leaflet is subject to change. Please check with your doctor whether there is any new information about this medicine that you should know since you were last treated.

What Intragam® 10 is used for

Your medicine is Intragam® 10, a solution for intravenous infusion. Intragam® 10 contains human immunoglobulins and is manufactured from human plasma (the liquid component of blood) collected by Australian Red Cross Lifeblood. Immunoglobulins are also called antibodies and are a type of protein found in the blood. Immunoglobulins are produced by your body's immune system to fight infections caused by bacteria and

viruses. If you do not have enough antibodies you may not be able to fight off diseases.

Your doctor may give you Intragam® 10 either for:

- the replacement of antibodies because your antibody levels are low (referred to as immunodeficiency), or
- a condition where there is an imbalance in your immune system requiring treatment with antibodies (referred to as immunomodulation).

Your doctor may have prescribed Intragam® 10 for another reason. Ask your doctor if you have any questions about why Intragam® 10 has been prescribed for you.

Before you are given Intragam® 10

Make sure you tell your doctor of any reasons you know of why you should not be given this medicine.

Inform your doctor of your blood group, if known.

You must not be given this medicine if you have:

- a history of allergy to human immunoglobulin products (allergic reactions may include skin rash, face swelling, wheezing or breathing difficulties) or previously been told you react to any of the ingredients in Intragam® 10 (human immunoglobulins or glycine)
- been told you have antibodies to immunoglobulin A (IgA)

Tell your doctor if you have, or have had, any of the following medical conditions:

- allergy to human immunoglobulin products or to glycine. Some of the symptoms of an allergic reaction may include rash, itchiness, swelling of the lips and tongue, shortness of breath.
- allergies to any other medicines, or if you have ever had an allergic reaction to an injection
- a history of heart, or blood vessel disease, or blood clots, have thick blood, have been immobile for some time. Also tell the doctor what medicine you are using as some medicines, such as those that contain the hormone estrogen (for example, birth control pills), may increase your risk of developing a blood clot.
- high blood pressure
- low blood volume (hypovolaemia)
- a condition that causes low antibody levels in your blood (IgA deficiency, hypogammaglobulinaemia or agammaglobulinaemia with or without IgA deficiency)
- diabetes
- kidney problems or kidney disease
- a history of frequent headaches or migraine
- any other medical conditions.

It is also important that you tell your doctor if you:

- have blood group A, B or AB
- are pregnant, intending to become pregnant or are breast-feeding

- have had any vaccination within the last two weeks
- are dehydrated
- are taking any other medicines, including herbal or complementary medicines.

How Intragam® 10 is given

Your doctor will determine the dose(s) of Intragam® 10 that you will receive. Intragam® 10 is administered as an intravenous infusion (an injection given slowly into a vein).

On the day of your infusion make sure you have had sufficient fluids which will help reduce the risk of side effects.

While you are having Intragam® 10

This medicine is not expected to affect your ability to drive a car or operate machinery.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you obtain without a prescription from your pharmacy, supermarket or health food shop.

Vaccinations: Please inform your doctor if you are planning to have a vaccination. Intragam® 10 may impair the effect of some virus vaccines such as measles, mumps, rubella and chicken pox for a period of at least 6 weeks, and up to 3 months. After receiving this medicine, a period of 3 months should be allowed before vaccination with some virus vaccines. In the case of measles vaccine, this effect may last for up to 1 year, so if you are going to receive a measles vaccine you

should have your measles antibody status checked.

Things you must do:

- If you experience any of the effects listed in the side effects section of this leaflet or any other abnormal signs after treatment, tell your doctor immediately.
- If you are about to be started on any new medicine, remind your doctor that you have been given Intragam® 10. Tell any other doctors, dentists, and pharmacists who treat you that you have been given this medicine.
- If you are about to have any blood tests, tell your doctor that you have been given this medicine. It may interfere with the results of some tests.

Things to be careful of:

- If having an infusion makes you feel light headed, dizzy or faint, be careful when getting up from a sitting or lying position. Getting up slowly may help.
- Some patients may develop delayed reactions to Intragam® 10. These reactions occur after the infusion has stopped but usually within 24 hours.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are being given Intragam® 10, even if you do not think how you feel is connected with your medicine.

Along with their intended effects, medicines occasionally cause unwanted effects (side effects) in some people, some of which are serious. Side effects are more common with the first dose of Intragam® 10. Different people may react differently to similar doses of the same product. This

applies to Intragam® 10. Most side effects tend to be related to the rate of infusion and are likely to occur during the first hour of infusion. If a side effect occurs, the nurse or doctor may reduce the rate of infusion or the infusion may be stopped.

If you are over 65 years you may have an increased chance of experiencing a side effect.

Do not be alarmed by the following lists of possible side effects. You may not experience any of them. If you have any questions, ask your doctor.

Tell your doctor if you notice any of the following:

This list includes the more common side effects of Intragam® 10. They are usually mild and short-lived.

- headache
- nausea
- lethargy
- pain in a joint
- vomiting
- pain in a muscle
- infusion site reaction/pain
- fever
- dizziness
- pain
- hot flush
- migraine
- musculoskeletal stiffness
- itchiness
- pain in the abdomen
- rash
- skin peeling and redness
- diarrhoea
- paleness of skin
- increased heart rate.

If you experience any of the following, tell your doctor immediately or go to the Emergency Department at your nearest hospital:

- decreased alertness or difficulty in speaking
- tingling, numbness or weakness on one or both sides of the body

- pain/tenderness, swelling/dicolouration of an arm or leg
- shortness of breath
- chest pain
- skin becoming yellow
- dark urine
- decreased urine.

In rare cases this type of medicine may cause a sudden fall in blood pressure or a condition called anaphylactic shock, which is an allergic reaction that has symptoms such as low blood pressure (feeling faint) and difficulty breathing.

Severe headache, neck stiffness, drowsiness, fever, inability to stand bright light or painful eye movements may occasionally occur after receiving this medicine.

This list includes very serious side effects. You may need urgent medical attention or hospitalisation if you experience any of these side effects.

Other side effects not listed above, including inflammation of blood vessels and change in liver function, may also occur in some people. Some of these side effects may not cause symptoms and may only be found when your doctor does tests from time to time to check your progress.

Important information about some of the ingredients in Intragam® 10

When medicines are made from human blood or plasma, processes are used to prevent infections being passed from the blood/plasma donor to the person receiving the medicine. These processes include careful selection of the people who donate blood and plasma to make sure that those who might be carrying infections are excluded. In addition, each donation and pools of

donations are tested for indicators of virus/virus infection(s).

Manufacturers of these medicines also include steps in the processing of blood or plasma that inactivate or remove viruses. Despite these processes, when medicines are prepared from human blood or plasma, the possibility of passing on an infection cannot be totally ruled out. Unknown or new viruses or other types of infection could also be passed on.

However, the measures taken in the manufacture of this medicine are considered effective for enveloped viruses such as human immunodeficiency virus, hepatitis B virus, and hepatitis C virus, and for the non-enveloped viruses hepatitis A and B19 virus (B19V).

There is reassuring clinical experience regarding the lack of hepatitis A or B19V infections with immunoglobulins. The antibodies which are in Intragam® 10 may make an important contribution to limiting the possibility an infection could also be passed on.

Please discuss the risks and benefits of this product with your doctor.

If you receive too much (overdose)

As Intragam® 10 is given to you under the supervision of your doctor or trained medical professional, it is very unlikely that you will receive an overdose. If you experience any side effects, tell your doctor immediately.

Further information

Intragam® 10 can only be obtained on a doctor's prescription. This leaflet does not contain all the available information about Intragam® 10. If you require further information about Intragam® 10 and your treatment generally, or if you have any questions or are not

sure about something in this leaflet, consult your doctor.

Storing Intragam® 10

You will normally be given this medicine in hospital. You will probably not need to keep any bottles of Intragam® 10. However, if you have to keep this medicine at home it should be stored refrigerated (2°C to 8°C) but not frozen. Once removed from refrigeration, store below 25°C and use within 3 months. Protect this medicine from light by keeping the bottles in their cartons.

Disposal

If your doctor stops your treatment or this medicine has passed its expiry date, ask your hospital or pharmacist what to do with any that is left over.

Product description

What it looks like

Intragam® 10 is a clear, colourless or pale yellow liquid. It is supplied in glass bottles.

Ingredients

Intragam® 10 is a sterile solution containing 10% plasma proteins of which at least 98% are immunoglobulins. Intragam® 10 does not contain any preservatives. Intragam® 10 is packaged in latex free materials.

Manufacturer

Intragam® 10 is manufactured in Australia by:

CSL Behring (Australia) Pty Ltd
 ABN 48 160 734 761
 189–209 Camp Road
 Broadmeadows VIC 3047
 Australia

Distributor

Australian Red Cross Lifeblood

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Australian Register Numbers

25 mL: AUST R 162486

50 mL: AUST R 162487

100 mL: AUST R 162488

200 mL: AUST R 162489

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